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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:

Yoshio HIRAKI et al

: GROUP ART UNIT: 1617

SERIAL NO.: 09/913,721

: EXAMINER: Gina YU

FILED: August 17, 2001

FOR: SKIN PREPARATIONS FOR EXTERNAL USE

DECLARATION UNDER 37 C.F.R. §1.132

ASSISTANT COMMISSIONER FOR PATENTS  
WASHINGTON, D.C. 20231

SIR:

Now comes Takashi Kinoshita who deposes and states that:

1. I am a graduate of Waseda university and received my bachelor degree in the year 1996.
2. I have been employed by Yakult Honsha Co., Ltd. for 6 years as a researcher in the field of chemistry.

3. Lamellar compositions of the present invention and Comparative compositions equivalent to those described in Maybeck et al. (Examples 1 and 3) were prepared and compared according to the following:

Fatty acid monoglyceride ("Poem S-100", *Riken Vitamin Co., Ltd.*), cholesterol ("Cholesterol JSCI", *Nippon <sup>Seika</sup> ~~Sika~~ Co., Ltd.*), tretinoin (trans-retinoic acid, *Sigma Limited*) and Vitamin E ("Emix 70L", *Esai Co., Ltd.*) were mixed together according to each formulation

of Examples 1 and 3 as shown in Table 2. The mixture was heated at 60°C and dissolved, and thereafter, oil layers 1 and 3 were obtained, respectively.

Soybean lecithin ("Lecinol S-10", *Nikko Chemicals Co.*), cholesterol ("Cholesterol JSCI", *Nippon <sup>Seika T.K.</sup> ~~Sika~~ Co., Ltd.*), tretinoin (trans-retinoic acid, *Sigma Limited*) and Vitamin E ("Emix 70L", *Esai Co., Ltd.*) were mixed together according to each formulation of Examples 2 and 4 as shown in Table 2. After the mixture was heated up to 60°C, 60°C purified water was added thereto (10% by weight of the total mixture) to obtain oil layers 2 and 4.

After oil layers 1 to 4 were dissolved into 60°C purified water, each solution was stirred at 8000 r.p.m. by a homomixer at 60°C for 5 minutes, and then cooled down to 32°C to obtain target compositions (Examples 1 to 4).

The compositions thus obtained (Examples 1 to 4) were analyzed to determine whether lamellar structure and aggregation have been actually generated in these compositions. This analysis was performed under the criteria described in Table 1, and the results are shown in Table 2.

TABLE 1

<u>Lamellar structure</u>
A: A large amount of lamellar structure was observed.
B: A small amount of lamellar structure was observed.
C: A trace amount of lamellar structure was observed.
<u>Aggregation</u>
A: Aggregation was not generated.
B: Aggregation was generated.

TABLE 2

	Present invention		Maybeck et al.	
	Example 1	Example 3	Example 2	Example 4
Fatty acid monoglyceride (Poem S-100)	1.0 g 100%	5.0 g 50%	----	----
Soybean lecithin~ (Lecinol S-10)	----	----	1.0 g	5.0 g
Cholesterol (Cholesterol JSCI)	0.3 g 10%	1.5 g	0.3 g	1.5 g
Tretinoin (trans-retinoic acid)	0.01 g 1%	1.00 g	0.01 g	1.00 g
Vitamin E (Emix 70L)	0.003 g	0.015 g	0.003 g	0.015 g
Purified water	98.687 g	92.985 g	98.687 g	92.985 g
Generation of lamellar structure	B	A	C	B
Generation of aggregation	A	A	B	B

4. The results obtained above indicate that the composition of the present claims is superior in generation of lamellar structure and superior in generation of aggregation, which is an indication of how effectively the oil phase mixture is formed, as compared to examples equivalent to those described in Maybeck et al. (Examples 1 and 3).

5. The undersigned petitioner declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

6. Further deponent saith not.

Takashi Kinoshita  
Signature

September 20, 2002  
Date